GOLDSTEIN & RUSSELL, P.C.

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April 13, 2017

[VIA CM/ECF]

Molly Dwyer, Clerk of Court
Office of the Clerk
U.S. Court of Appeals for the Ninth Circuit
P.O. Box 193939
San Francisco, CA 94119-3939
(415) 355-8000

Re: Supplemental authority in *Campie v. Gilead Sciences, Inc.*, No. 15-16380

Dear Ms. Dwyer,

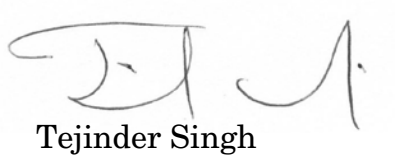
This letter responds to Gilead Sciences' most recent 28(j) letters.

The February 21 letter cites *U.S. ex rel. Kelly v. Serco, Inc.*, 846 F.3d 325 (9th Cir. 2017), which found no materiality at summary judgment on clear evidence that allegedly falsified progress reports did not matter. Indeed, the government itself had stopped requiring these reports "because [they] provided minimal benefit and [were] not cost-justified." *Id*. at 334. Thus, the government agreed to accept reports in the form provided by the defendant, and knowingly paid vouchers accompanying those reports. *Id*. *Kelly* is an egregious example of non-materiality. But it does not help Gilead because there has been no discovery here, and our pleadings allege that the government is concerned about the veracity of drug approval applications, as well as the composition and origin of the prescription drugs it pays for. *E.g.*, E.R.130 ¶ 109; E.R.138 ¶ 142.

The April 11 letter cites *D'Agostino v. ev3, Inc.*, 845 F.3d 1 (1st Cir. 2016). There, the manufacturer of a medical device made statements during the approval process that the device was to be used for narrow purposes by physicians with substantial training. It turned out that the device was being used for off-label purposes and by physicians with little or no training. The complaint alleged that the approval process representations "'could have' influenced the FDA to grant that approval." *Id*. at 7. The First Circuit found this speculative allegation fell "short of pleading a causal link between the representations made to the FDA and the payments made by CMS." *Id*. The court noted that the FDA had taken no action to remove the product or sanction the manufacturer despite knowing of the allegations for six years. *Id*. at 8. This case is different because: (1) to the extent we rely on fraud on the FDA, the causal link is pleaded explicitly, E.R.146 ¶168; (2) the FDA recalled some of Gilead's medicines and found problems with others, E.R.152

¶¶ 188-89; and (3) the FDA had no reason to take further action because Gilead stopped using Synthetics China's API in 2011, E.R.152 ¶ 189.

Respectfully submitted,



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CERTIFICATE OF SERVICE

I hereby certify that I electronically filed the foregoing with the Clerk of the Court for the United States Court of Appeals for the Ninth Circuit by using the appellate CM/ECF system on April 13, 2017.

I certify that counsel for Gilead and the United States are registered CM/ECF users and that service will be accomplished on them by the appellate CM/ECF system.

Service will be accomplished by electronic means to:

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/s Tejinder Singh